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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,923	05/14/2007	Manpreet S. Wadhwa	PC027698A	4848

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
11/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~ipgsstl@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,923	WADHWA ET AL.	
	Examiner	Art Unit	
	FOZIA M. HAMUD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1a. Receipt of Applicants' amendment and arguments, filed on 29 July 2009 is acknowledged.

Status of Claims:

1b. 1-15 are pending and under consideration.

Information Disclosure Statement:

2. The information disclosure statement filed on 29 July 2009 has been received and complies with the provisions of 37 CFR §1.97 and §1.98. The reference has been considered as to the merits.

Maintenance of previous Rejections:

Claim Rejections - 35 USC § 103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al (U.S. Patent 6,448,225, issued on 10 September 2002) in view of Patel, Suman, (US patent 5,358,708, issued on 25 October 1994), for reasons of record set forth in the office action mailed on 4/29/2009.

Applicants argue that the instantly claimed invention is directed to a formulation of human growth hormone comprising methionine and a polymer stabilizer. Applicants submit that neither O'Conner nor Patel teach the use of the polymer stabilizer in conjunction with methionine as required by the instantly claimed invention. Applicants submit that the polymer stabilizer required in the instantly claimed invention is selected from a polyethylene glycol or polyethylene glycol derivative. Applicants argue that O'Conner teaches the use of certain non-ionic surfactants such as a polysorbate, a poloxamer, polyols or ethylene/polypropylene block polymers, however, O'Conner does not disclose the use of a polyethylene glycol as a polymer stabilizer. Applicants contend that Patel teaches an interferon, a granulocyte-macrophage colony stimulating factor or an interleukin in an aqueous buffer also comprising methionine or histidine or a mixture thereof but makes no mention whatsoever of the use of a polymer stabilizer such as a polyethylene glycol or polyethylene glycol derivative.

These arguments have been considered, but are not found persuasive. Contrary to Applicants' argument, O'Connor et al teach a stable aqueous formulation of human growth hormone comprising non-ionic surfactants as well as pluronic or polyols, (see column 3, lines 36-40). A common polyol is polyethylene glycol, (see the attached Bio-Rad Laboratories, product sheet, page 1). As Applicants acknowledge Patel teaches an

interferon, a granulocyte-macrophage colony stimulating factor or an interleukin in an aqueous buffer that also comprises methionine.

Applicants submit that the obviousness rejection is based on combination of Patel et al, which teaches the use of methionine as a stabilizer without the use of a polymer stabilizer, with the O'Conner hGH formulation which lacks both the polymer stabilizer and methionine. Applicants conclude that one of ordinary skill in the art would not be motivated to modify the combination of O'Conner and Patel since the use of methionine as a stabilizer is not only protein specific, but can also be pH specific and is therefore methionine is not known as a common stabilizer. Applicants contend that the literature also discloses that the use of methionine as a stabilizer is very dependent upon the protein and the conditions of the formulation. Applicants contend that the use of methionine in formulating granulocyte macrophage colony stimulating factor referenced in Patel et al, has been shown to only be a stabilizer at acidic conditions and have no effect when formulating at alkaline conditions. Applicants submit that proper combination of O'Conner and Patel does not provide the instantly claimed invention and thus does not render it obvious.

These arguments have been considered, but are not found persuasive. As set forth above, the combined teachings of O'Conner et al and Patel et al render the claimed invention obvious, because O'Conner et al reference teaches hGH formulation which comprises polyol, while Patel et la teach formulations that use methionine. Applicants' argument that methionine is only effective in acidic conditions is irrelevant, because Patel teaches that adding methionine to the formulations extended storage

lifetimes. Furthermore, Patel teaches that methionine was used in acidic conditions, (see Example 3 and figure 4). Accordingly, the combined teachings of O'Conner et al and Patel et al render the claimed invention obvious.

Conclusion:

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
17 November 2009

/Bridget E Bunner/
Primary Examiner, Art Unit 1647